

PATENT COOPERATION TREATY

From the:
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Cullen & Co
GPO Box 1074
BRISBANE QLD 4001

PCT WRITTEN OPINION (PCT Rule 66)

Date of mailing
(day/month/year) **04 AUG 2004**

Applicant's or agent's file reference
021081PC/KF

REPLY DUE within **TWO MONTHS**
from the above date of mailing

International Application No.
PCT/AU2003/001552

International Filing Date (day/month/year)
20 November 2003

Priority Date (day/month/year)
20 November 2002

International Patent Classification (IPC) or both national classification and IPC
Int. Cl. ⁷ G01N 33/53, 35/00

Applicant

BIO-MOLECULAR HOLDINGS PTY LIMITED et al

1. This written opinion is the **first** drawn by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

- I ☒ Basis of the opinion
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☒ Certain observations on the international application

3. The **FINAL DATE** by which the international preliminary examination report must be established according to Rule 69.2 is:
20 March 2005

4. The applicant is hereby invited to reply to this opinion.

When? See the **Reply Due** date indicated above. However, the Australian Patent Office will not establish the Report before the earlier of (i) a response being filed, or (ii) one month before the **Final Date** by which the international preliminary examination report must be established. The Report will take into account any response (including amendments) filed before the Report is established. **If no response is filed by 1 month before the Final Date, the international preliminary examination report will be established on the basis of this opinion.**

Applicants wishing to have the benefit of a further opinion (if needed) before the report is established should ensure that a response is filed at least 3 months before the **Final Date** by which the international preliminary examination report must be established.

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3.
For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis.
For an informal communication with the examiner, see Rule 66.6.

Name and mailing address of the IPEA/AU
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WRITTEN OPINION

International application No.

PCT/AU2003/001552

I. Basis of the opinion

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the written opinion was drawn on the basis of the sequence listing:

- ☐ contained in the international application in printed form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed"*

WRITTEN OPINION

International application No.

PCT/AU2003/001552

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	YES
	Claims 1-2	NO
Inventive step (IS)	Claims	YES
	Claims 1-2	NO
Industrial applicability (IA)	Claims 1-2	YES
	Claims	NO

2. Citations and explanations

WO 2001/067102 A (THE REGENTS OF THE UNIVERSITY OF CALIFORNIA) 13 September 2001—Abstract; page 4, lines 16-25; page 5, lines 14,15; page 6, line 1 - page 7, line 4; page 24, line 4
 WO 1995/031731 A (GAMMA BIOLOGICALS, INC) 23 November 1995—Abstract; page 3, lines 13-15, lines 25-31
 NEW CITATION: US 3763374 A (TIFFANY et al.) 2 October 1973

NOVELTY (N), INVENTIVE STEP (IS) CLAIMS 1-2

Claims 1 and 2 are not novel and do not involve an inventive step because both the WO citations disclose binding assays by optical measurements (e.g. of fluorescence) of the binding interaction in a centrifuge.

New US citation discloses a dynamic multistation photometer-fluorometer for simultaneously determining solute concentration in a multiplicity of discrete samples. A multiplicity of sample analysis chambers or cuvettes are arranged in a circular array within a centrifuge rotor to provide a rotary cuvette system. A photometer light source and a photodetector are disposed on opposite sides of the centrifuge rotor. As well a fluorescence excitation light source is disposed on the same side of the rotor as the photodetector. This citation appears to disclose the invention as described, illustrated and claimed. Consequently claims 1 and 2 are not novel and do not involve an inventive step.

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. The claims are not clear as the terms "partner" and "interaction" are vague. Perhaps terms like "molecular chemical entity" and "binding" would make the claims clearer.
 2. The claims are not clear about the term "rotor". In mechanical technology, the term "rotor" is commonly used for a rotating assembly of blades (as in a turbine)—which is not the meaning in here. Perhaps a term such as "an annular rotating member" or "the rotating chamber of a centrifuge" would make the claims clearer.
 3. In consequence of observation 2, the term "at or near the periphery thereof" is not clear in relation to the rotor.
 4. It is not clear from the claims that the reaction wells are attached to the rotor and rotate therewith.
 5. It is not clear from the claims that the "system for detecting light" is positioned as shown in figure 1, i.e. the system for detecting light is stationary and it detects light as each reaction well passes near it as a result of the rotation of the rotor and the consequent motion of the reaction well.
- The applicant is invited to insert into the description references to the prior art cited in the International Search Report and this International Preliminary Examination Opinion, and to discuss the invention in relation to this prior art, so as to put the invention into proper perspective.